UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SHUANG LIU, JOHN A. BARRETT, and ALAN P. CARPENTER

Appeal No. 2005-2132
Application No. 09/899,629

ON BRIEF

Before ADAMS, GREEN, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

VACATUR and REMAND TO THE EXAMINER

On consideration of the record, we find this case is not in condition for a decision on appeal. For the reasons that follow, we vacate[1] the pending rejections and remand the application to the examiner to consider the following issues and to take appropriate action.

Claims 19-22, 30-33, and 35-39 are before us on appeal. The remaining claims, claims 1-18, 23-29, 34, and 40-92 have been withdrawn from

[1] Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

consideration as a result of a Restriction Requirement. See Papers mailed December 12, 2002 and October 28, 2003.

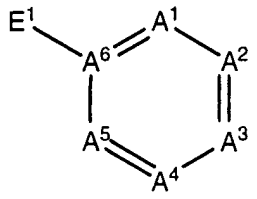
Claim 19 is illustrative of the subject matter on appeal and is reproduced below:

19. A pharmaceutical composition comprising:

(1.) a radiolabeled pharmaceutical agent of the formula (II)

$$RI\text{-}Ch^{[2]}\text{-}L_n\text{-}(BM)_x \qquad \text{(II); and}$$

(2.) an effective stabilizing amount of a compound of formula (I):



wherein

RI is ^{99m}Tc, ^{131}I, ^{125}I, ^{123}I, ^{177m}Sn, ^{111}In, ^{97}Ru, ^{203}Pb, ^{67}Ga, ^{68}Ga, ^{89}Zr, ^{90}Y, ^{177}Lu, ^{149}Pm, ^{153}Sm, ^{166}Ho, ^{131}I[3], ^{32}P, ^{211}At, ^{47}Sc, ^{109}Pd, ^{105}Rh, ^{186}Re, ^{188}Re, ^{60}Cu, ^{62}Cu, ^{64}Cu, ^{67}Cu;

C_h is a metal chelator or is a direct linkage;

L_n is a linking group or is a direct linkage;

each BM is independently an antibody, an antibody fragment, a peptide, a peptidomimetic, or a non-peptide;

x is 1 to about 10;

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[2] We note that this claim uses different nomenclature in reference to this term. The claim refers to the term "Ch" in formula (II), and as "C_h" in defining the term as a metal chelator or in a direct linkage. We encourage the examiner and appellants to work together to ensure that the nomenclature used in the claims is consistent.

[3] It appears that this occurrence of ^{131}I is redundant to the first occurrence of ^{131}I in this clause. Accordingly, we encourage the examiner and appellants to work together to correct this redundancy.

E^1 is NH_2 or OH;

A^1, A^2, A^3, A^4 and A^5 are each independently N, C(OH) or CR^1;

provided at least one of A^1, A^2, A^3, A^4 and A^5 is not CH;

each R1 is independently H, $C(O)R^2$, $C(O)OR^2$, $NHC(=O)NHR^2$, $NHC(=S)NHR^2$, $OC(=O)R^2$, $OC(=O)OR^2$, $S(O)_2OR^2$, $C(O)NR^3R^4$, $C(O)NR^3OR^4$, $C(O)NR^2NR^3R^4$, NR^3R^4, $NR^3C(O)R^4$, $PO(OR^3)(OR^4)$, $S(O)_2NR^3R^4$, $S(O)_2NR^2NR^3R^4$, $S(O)_2NR^3OR^4$, C_1-C_{10} alkyl substituted with 0-5 R^5, C_3-C_{10} cycloalkyl substituted with 0-5 R^5, C_2-C_{10} alkenyl substituted with 0-5 R^5, or aryl substituted with 0-5 R^5;

R^2, R^3, and R^4 are each independently H, C_1-C_6 aikyl [sic], C_3-C_6 cycloalkyl, C_1-C_6 alkenyl, benzyl, or phenyl; or R^3 and R^4 together form C_3-C_{10} cycloalkyl or C_3-C_{10} cycloalkenyl, optionally interrupted with O, S, NH, S(=O), $S(O)_2$, P(=O)(OH), C(=O)NH, NHC(=O), NHC(=O)NH, or NHC(=S)NH; and

each R^5 is independently H, NH_2, OH, CO_2H, $C(=O)NH_2$, C(=O)NHOH, $C(=O)NHNH_2$, $NHC(=NH)NH_2$, $NHC(=O)NH_2$, $NHC(=S)NH_2$, PO_3H_2, SO_3H, or $S(O)_2NH_2$;

or a pharmaceutically acceptable salt thereof;

provided the compound of formula (I) is not (1) a substituted monohydroxyl aromatic compound; (2) a substituted dihydroxyl aromatic compound, in which the two hydroxyl groups are not adjacent to each other; (3) a substituted monohydroxyl-monoamino aromatic compound, in which the hydroxyl group and amino group are not adjacent to each other; or (4) an ortho, meta, or para aminobenzioc [sic] acid.

The references relied upon by the examiner are:

Vanderheyden et al. (Vanderheyden)	5,679,318	Oct. 21, 1997
Toner et al. (Toner)	5,707,603	Jan. 13, 1998
Sworin et al. (Sworin)	5,750,088	May 12, 1998
Rajopadhye et al. (Rajopadhye)	6,537,520	Mar. 25, 2003
Yoshinaga	JP 56-144060	Nov. 10, 1981

(the examiner relies on PTO:200-5-2710, a translation of this document)[4]

[4] We note that the examiner refers to this document alternatively as "Nippon Oils" and "Nippos Oils and Fats."

GROUNDS OF REJECTION[5]

Claims 19-22, 30-33 and 35-39 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, and 28-30 of Rajopadhye in view of Vanderheyden and Yoshinaga.

Claims 19-22, 30-33 and 35-39 stand rejected under 35 U.S.C. § 103 as being unpatentable over Sworin or Toner in view of Vanderheyden and Yoshinaga.

For the following reasons, we vacate the pending rejections and remand the application to the examiner for further consideration.

DISCUSSION

Obviousness-type Double Patenting:

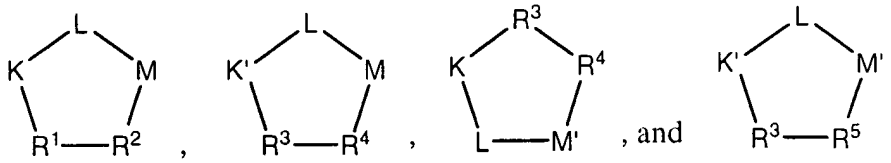
The examiner finds (Answer, page 4), Rajopadhye "claims a pharmaceutical composition, or kit, comprising the radionucleode herein." According to the examiner (id.), Rajopadhye does not teach stabilizers. To make up for this deficiency, the examiner relies on Vanderheyden to teach (id.), "that therapeutical radionuclide compositions generally require the presence of stabilizer." In addition, the examiner relies on Yoshinaga to teach that "gallic acid is a knonwn antioxidant, and are [sic] suitable for human consumption." Id.

We find, however, no discussion in the Answer, or the Final Office Action, mailed April 15, 2004, as to how claims 22, and 28-30 of Rajopadhye relate to "a

[5] We note that the examiner withdrew the rejection of claims 19-22, 30-33 and 35-39 under 35 U.S.C. 103 as being unpatentable over Rajopadhye in view of Vanderheyden and Yoshinaga.

radiolabeled pharmaceutical agent of formula (II)" as set forth in appellants' claimed invention. For example, appellants' claim 19 requires that the "BM" component of formula (II) is "independently an antibody, an antibody fragment, a peptide, a peptidomimetic or a non-peptide.[6] Claims 28-30 of Rajopadhye as relied upon by the examiner depend from claim 27. Claim 27 of Rajopadhye is drawn, inter alia to a

> therapeutic radiopharmaceutical composition ... wherein the compound is of the formula:
>
> $$(Q)_d\text{-}L_n\text{-}C_h \text{ or } (Q)_d\text{-}L_n\text{-}(C_h)_d$$
>
> wherein, Q is a peptide independently selected from the group:



As can be seen from the claim 27[7] of Rajopadhye, each of the peptides defined by component "Q" are cyclic peptides. In contrast, when component "BM" of appellants' formula (II) is a peptide, appellants' specification defines a "peptide" as "a linear compound having two or more amino acids ... that are linked by means of a peptide bond." Appellants' specification, page 26. Therefore, it is unclear on this record how the cyclic peptides set forth in claims 22 and 28-30 of Rajopadhye relate to component "BM" of appellants' claimed invention.

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[6] While we focus on component "BM" we find no analysis by the examiner as to what appellants intend by use of the term "linker" and how appellants' linker relates to the linkers set forth in claims 22 and 28-30 of Rajopadhye.

[7] To be complete, we recognize the examiner's reliance on claim 22 of Rajopadhye. Claim 22 of Rajopadhye depends from claim 19, which also defines component "Q" as a cyclic peptide as in claim 27.

For the foregoing reasons, we vacate the obviousness-type double patenting rejection and remand the application to the examiner to clarify how each element of appellants' claimed invention relates to the combination of claims 22 and 28-30 of Rajopadhye in view of Vanderheyden. In this regard, we encourage the examiner to review MPEP § 706.02(j) for a model of how to explain an obviousness rejection. Adherence to this model will of necessity require that the examiner consider the patentability of the claims in an individual manner and set forth the facts and reasons in support of why individual claims are unpatentable.

Obviousness:

The examiner relies on Sworin and Toner in the alternative to teach "radionuclide conjugates wherein the radionuclide attached to a peptide, or protein, or peptidomimetic moiety through a chelator moiety."[8] Answer, page 7. In both instances, the examiner directs attention to the abstract and claims of the references. However, like the statement of the rejection in the obviousness-type double patenting rejection, the examiner provides no explanation as to how the references relate to each component of appellants' claimed invention in either the Answer, or the Final Office Action, mailed April 15, 2004.

[8] According to the examiner (Answer, page 7), "[t]he primary references do not teach expressly adding stabilizers ... in the radionuclide conjugate composition." To make up for this deficiency, the examiner relies on Vanderheyden to teach "that therapeutical radionuclide compositions generally required the presence of stabilizers." Id. In addition, the examiner relies on Yoshinaga to teach that "gallic acid is a known antioxidant ... suitable for mammal [sic] consumption." Id.

In this regard, we note that the examiner has the initial burden of presenting a factual basis to support a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Accordingly, we vacate the rejection under 35 U.S.C. § 103 and remand the application to the examiner to clarify how each element of appellants' claimed invention relates to the combination Sworn or Toner in view of Vanderheyden and Yoshinaga. In this regard, we encourage the examiner to review MPEP § 706.02(j) for a model of how to explain an obviousness rejection. Adherence to this model will of necessity require that the examiner consider the patentability of the claims in an individual manner and set forth the facts and reasons in support of why individual claims are unpatentable.

Elected Subject Matter:

In the Office Action dated December 12, 2002, in addition to requiring appellants to elect a single invention from the examiner's grouping of twelve distinct inventions, the examiner required appellants to elect, inter alia, a single disclosed species of RI, C_h, L_n, BM, and A^1-A^6. In their response, dated July 9, 2003, appellants elected ^{90}Y for RI, a chelator for C_h, a linking group for L_n, a peptide as BM and trihydroxybenzoic acid for components E^1 and A^1-A^6. However, while the Final Office Action, dated April 15, 2004 refers (see page 4) to gallic acid and/or gentisic acid there is no discussion of trihydroxybenzoic acid, appellants' elected species. It is not until the examiner responds to the arguments set forth in appellants' Brief (see Answer, pages 5, and 8), that the

examiner address appellants' elected species of the compound of formula (I) -- trihydroxybenzoic acid. It is unclear to the merits panel why the examiner waited until this extremely late stage of prosecution to address appellants' elected species. Accordingly, prior to taking any further action on the merits, we encourage the examiner to take a step back and reconsider appellants' claimed invention together with the relevant prior art and prosecution history of this application. If, after having the opportunity to review the record together with the available prior art, the examiner believes that a rejection is necessary he should issue an appropriate Office Action clearly, and articulately addressing each limitation of appellants' claimed invention, as encompassed by appellants' elected species. In this regard, we encourage the examiner to review MPEP § 706.02(j) for a model of how to explain an obviousness rejection. Adherence to this model will of necessity require that the examiner consider the patentability of the claims in an individual manner and set forth the facts and reasons in support of why individual claims are unpatentable.

REMANDED

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Demetra J. Mills)
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